March 21, 2005

Anne P. LeHuray, Ph.D.
Technical Contact
American Chemistry Council
Specialty Acrylate & Methacrylate Panel
1300 Wilson Boulevard
Arlington, VA 22209

Dear Dr. LeHuray:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-Propenoic acid, zinc salt (zinc acrylate) posted on the ChemRTK HPV Challenge Program Web site on February 11, 2004. I commend the Specialty Acrylate & Methacrylate Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
2-Propenoic Acid, Zinc Salt

Summary of EPA Comments

The sponsors, the Specialty Acrylates & Methacrylates (SAM) Panel of the American Chemistry Council, submitted a test plan and robust summaries to EPA for 2-propenoic (acrylic) acid, zinc salt (zinc acrylate, CAS No. 14643-87-9) dated December 22, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 11, 2004. The submitter also provided Information on the proposed analog acrylic acid (CAS No. 79-10-7).

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. The submitter needs to provide additional justification for relying on acrylic acid data. The submitter needs to address zinc toxicity and provide evidence that data for the individual dissociation products would adequately account for their relationship to toxicity and would represent the toxicity of zinc acrylate.

2. Physicochemical Properties. The submitter needs to provide partition coefficient and water solubility values for zinc acrylate.

3. Environmental Fate. The data provided on acrylic acid for these endpoints are adequate for the purposes of the HPV Challenge Program. However, the submitter needs to provide technical discussions on photodegradation, stability in water, biodegradation, and fugacity for zinc acrylate rather than acrylic acid.

4. Health Effects. (a) EPA reserves judgement on the applicability of the data submitted for acrylic acid for acute, repeated-dose and reproductive toxicities and chromosomal aberrations pending receipt of additional justification as stated above. (b) EPA reserves judgement on the adequacy of the gene mutations data submitted for zinc acrylate pending receipt of critical information.

5. Ecological Effects. The submitter needs to provide data for zinc acrylate or present adequate justification for using only acrylic acid data.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 2-propenoic Acid, Zinc Salt
Challenge Submission

Analog Justification

EPA agrees that zinc acrylate will dissociate in aqueous environments at low concentrations to the zinc ion (Zn(II)) and acrylate ion ($acrylate^{-1}$). An approach based on this behavior may be more readily supportable for evaluation of aquatic toxicities. However, in the evaluation of mammalian toxicities, especially via dermal or inhalation routes, complete dissociation is less likely. Also, for more concentrated solutions of zinc acrylate, metal-ligand complexes are significant and cannot be ignored.

The submitter needs to provide comparable studies on the salt and its dissociation products, or other evidence, to show that studies of the individual dissociation products would account for their relationship to toxicity and would adequately represent the toxicity of zinc acrylate (the submission did not address the toxic effects of zinc ion).

Once the issue of analog justification is resolved, further review of this submission will be conducted.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for melting point, boiling point, and vapor pressure are adequate for the purposes of the HPV Challenge Program.

Partition coefficient. The submitter indicates in its test plan that: "Because zinc acrylate is expected to dissociate rapidly to zinc and acrylic acid in environmental water compartments, the log K_{ow} for zinc acrylate is considered to provide no useful information for evaluation of environmental fate and effects. The log K_{ow} for acrylic acid is...considered adequate to meet the HPV Chemical Challenge Program requirements." EPA disagrees. Zinc acrylate dissociates to the zinc(II) and acrylate ions, not to zinc ions and acrylic acid. The log K_{ow} for acrylic acid is not an acceptable value for zinc acrylate. The submitter needs to provide modeled or measured Log Kow data for zinc acrylate, unless the submitter can demonstrate experimentally that zinc acrylate is water-miscible in all proportions.

Water solubility. The test plan states that acrylic acid is miscible with water and therefore zinc acrylate is also considered to be miscible with water. No supporting experimental data for zinc acrylate were provided. Although zinc acrylate is likely to be soluble to some unknown extent, it is not expected to be miscible (soluble in all proportions). For example, the water solubility of zinc propionate is 32 g/L and of zinc acetate is 303 g/L. The submitter needs to provide measured water solubility data for zinc acrylate following OECD Guideline 105.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The acrylic acid data provided by the submitter for photodegradation, stability in water, biodegradation and fugacity are adequate for the purposes of the HPV Challenge Program. However, as zinc acrylate dissociates to zinc(II) and acrylate ions, not into zinc ions and acrylic acid, the submitter needs to provide a technical discussion of this issue, and address how zinc acrylate (not acrylic acid) will behave with respect to photodegradation, stability in water, biodegradation, and environmental transport/distribution.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitted acute, repeated-dose and developmental inhalation toxicity studies for acrylic acid are inadequate because of its local irritant action. EPA reserves judgement on the appropriateness of the data submitted for acrylic acid for acute, repeated-dose and reproductive oral toxicity studies and the chromosomal aberration assay pending receipt of additional information to support the use of this proposed analog.

Genetic toxicity. Gene mutations. EPA reserves judgement on the adequacy of the data submitted for zinc acrylate for gene mutations (Ames test) pending receipt of critical information missing from the robust summary.

Ecological Effects (fish, invertebrates, and algae)

EPA disagrees that adequate data exist for fish, daphnia and green algae. The submitter needs to provide toxicity data for zinc acrylate or submit adequate justification for using data on acrylic acid to represent zinc acrylate toxicity.

Specific Comments on the Robust Summaries

Human Health Effects

Genetic toxicity. Gene mutations. Information missing in the robust summary of an *in vitro* gene mutation study of zinc acrylate includes the purity of the test material, the cytotoxic concentration, and the number of replicates/concentration that were counted.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.